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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/645,967 08/24/00 YANG

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EXAMINER

HM12/0511

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ART UNIT

PAPER NUMBER

1624
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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/645,967

Applicant(s)

Yang et al.

Examiner

Bruck Kifle

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Aug 24, 2000
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-77 is/are pending in the application.
- 4a) Of the above, claim(s) 46-77 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 5 20) ☐ Other:

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-45, drawn to compounds of claims 1 and 20 and method of producing them, classified in class 540, subclass 456.
- II. Claims 46-76, drawn to a method for multimerizing chimeric proteins in cells, classified in class 435, various subclasses.
- III. Claim 77, drawn to a method of producing 28 epi, 29 epi or 28,29 bis-epi compounds of formula IV, classified in class 540, subclass 456.

The inventions are distinct, each from the other because of the following reasons: Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compounds can be used, for example, as antifungal agents.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Group III is of a different scope.

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Compounds, corresponding compositions, a method of use and a process of making that are of the same scope are considered to form a single inventive concept.

During a telephone conversation with Mr. David Bernstein on May 10, 2001 a provisional election was made with traverse to prosecute the invention of group I, claims 1-45. Affirmation of this election must be made by applicant in replying to this Office action. Claims 46-77, along with subject matter not falling under the same scope of the formula in claims 1 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claim 42 is only examined to the extent it covers compounds of claims 1 and 20.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Abstract

Applicant is reminded of the proper content of an Abstract of the Disclosure.

In chemical patent abstracts for compounds or compositions, the general nature of the compound or composition should be given as well as its use, *e.g.*, "The compounds are of the class of alkyl benzene sulfonyl ureas, useful as oral anti-diabetics." Exemplification of a species could be illustrative of members of the class. For processes, the type reaction, reagents and process conditions should be stated, generally illustrated by a single example unless variations are necessary.

Complete revision of the content of the abstract is required on a separate sheet.

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Claim Rejections - 35 USC § 112

Claims 1-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

i) In the definitions of R^{2b} and R^{43} , the phrase “substituted or unsubstituted aliphatic or acyl moiety” is indefinite. It is unclear what the intended substituents are and which ones are not permitted. It is unclear what the aliphatic or acyl moiety may or may not be. One cannot say which acyls are intended, whether acyls of sulfonic acid; arsenic or phosphoryl are all intended or not. If Applicants intention is only alkanoyl groups, then so should be stated. See also definitions of R^A and R^B for similar problem.

ii) In the definitions of R^A and R^B , the groups heteroaliphatic, aryl and heteroaryl are not clear. One cannot say which atoms are present, how many of each are intended or how many rings are present. The term “heteroaliphatic” is not normal nomenclature. What is intended?

iii) The metes and bounds of the “pharmaceutically acceptable derivative” is not known. One skilled in the art cannot say when a compound is no longer a derivative. The phrase “a pharmaceutically acceptable salt thereof” is suggested. Also, the phrase “and as an pharmaceutically acceptable derivative thereof” is improper Markush language. The term “or” is suggested.

iv) The phrase “as a substantially pure stereoisomer or mixture of stereoisomers” is confusing. The compounds are directed to a specific stereoisomer. What else is intended?

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v) Claim 42 is an independent claim. All of the limitations should be recited in an independent claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grinfield et al. (WO 98/09972). The reference teaches a group of rapamycin derivatives with unnatural stereochemistry which embraces applicants' claimed compounds (See pages 3-5, compounds of formula (I), definitions of the variables and configuration at the 28 and 43 positions, according to Applicant's numbering). The claims differ from the reference by reciting specific species and a more limited genus than the reference. However, it would have been obvious to one having ordinary skill in the art at the time of the invention to select any of the species of the genus taught by the reference, including those instantly claimed, because the skilled chemist would have the reasonable expectation that any of the species of the genus would have similar properties and, thus, the same use as taught for the genus as a whole. One of ordinary skill in the art would have been motivated to select the claimed compounds from the genus in the reference since such compounds would have been suggested by the reference as a whole. It has been held that a prior art disclosed genus of useful compounds is sufficient to render prima facie obvious a species


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falling within a genus. *In re Susi*, 440 F.2d 442, 169 USPQ 423, 425 (CCPA 1971), followed by the Federal Circuit in *Merck & Co. v. Biocraft Laboratories*, 847 F.2d 804, 10 USPQ 2d 1843, 1846 (Fed. Cir. 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruck Kifle whose telephone number is (703) 305-4484.

The fax phone number for this Group is (703) 308-4556 or (703) 305-3592. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

May 10, 2001


Bruck Kifle
Primary Examiner
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